EXHIBIT 27

December 9, 2010

Matthew P. Moriarty
925 Euclid Avenue
Cleveland, Ohio 44115-1414

Re: Digitek® Litigation – Quality Assurance Consultation

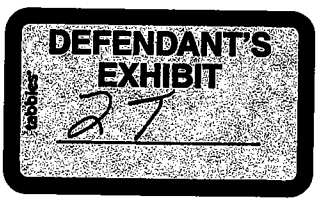
Dear Mr. Moriarty,

I have been provided with a number of documents to review that pertain to the manufacture, testing and disposition of Digitek® tablets in both the 0.125 mg and 0.25 mg dosage strengths. These documents include raw material records, drug product manufacturing and packaging records and their related testing records, validation reports, annual product reviews and annual reports submitted to FDA, as well as FDA documents (Form 484 sample collection records, Form 483 observations and warning letters, and the responses made by Actavis Totowa (Actavis)). Additionally, information from several other firms, UDL, Quantic Regulatory Services (Quantic) and Gibraltar Laboratories was also provided. I have reviewed these documents. Based on my review of these documents, I find no evidence to suggest that "double-thick" Digitek® tablets were released to the market. On a separate subject, I find no evidence to suggest that high-potency Digitek® tablets were released to the market.

Data Integrity and Product Integrity

The FDA made a number of observations on Form 483's (August 10, 2006 and October 11, 2006) and in a warning letter (February 1, 2007) about laboratory practices at Actavis. Based on a review of the relevant observations and the Actavis responses, the issues revolve around the manner in which out of trend or out of specification test results were being documented and in how the investigations were being documented, and not on data integrity. It should be noted that an independent audit of a number of Actavis batch records by Quantic revealed no deficiencies in the records that would cast doubt on the manufactured product. My own review of 12 Actavis batch records yielded the same results.

The use of the term "adulterated" in FDA warning letters, based on Federal Food, Drug, and Cosmetic Act (FD&C) section 501 (a)(2)(B) [21 USC §351], is a technical term that refers to conformance to Current Good Manufacturing Practice (cGMP). It is not necessarily used in the sense of "contaminated" or "impure". If, for example, a firm discarded certain manufacturing records a year earlier than required to maintain them, their product could theoretically be considered adulterated. FDA's use of the term "adulterated" in conjunction with cGMP deficiencies does not inherently imply impure or defective product.



The Process

Digitek® tablets are produced by a direct compression process. That is, the tablets are compressed directly from the blended powders (Digoxin, USP and the other ingredients), without undergoing a granulation process. No liquids are added and the powders are blended using several rotating containers to mix the powders via a tumbling action. After the final blending step, samples are taken to the lab for blend uniformity testing (samples are withdrawn from 10 locations in the blender and each sample separately tested for percentage of digoxin versus label claim). After blend uniformity testing, the blend is then transferred to tabletting machines (one or two may be used during the compression process). Periodically during the compression process, samples are collected for various in-process tests. Production personnel perform weight, thickness, hardness and appearance checks. Quality Assurance (QA) also periodically performs weight, thickness, hardness and appearance checks. Additionally, the lab performs finished product testing for:

- friability (tablet weight loss via abrasion after being subjected to rolling/falling in a specialized apparatus)
- content uniformity (the percentage of digoxin versus label claim in each of 10 individual tablets)
- assay (the percentage of digoxin versus label claim from a composite sample of a number of tablets – the tablets are ground and from the composited, ground tablets a portion is taken for the test, with a single value reported)
- dissolution (the percentage of digoxin versus label claim in each of 6 individual tablets after the tablets have been subjected to a bath in a liquid medium for a specified period of time)
- related substances (the percentage of certain compounds related chemically to digoxin that might be present in the tablets)
- identity (2 chemical tests that confirm the presence of digoxin in the tablets)

Batches of packaged product are periodically sampled for stability testing. Such packaged product samples are stored in special temperature and humidity-controlled chambers. At specified intervals, samples are withdrawn from the chambers for testing.

Data

A summary of the data review follows. I note at this point that the reason for the recall of unexpired lots of Digitek® tablets was a concern that double thick tablets may have been commercially released. This was FDA's concern. They expressed no concern about high potency lots of normal size-tablets being released. A double thickness tablet would have high potency. Such a tablet, however, would be a result of a tablet compression incident. For normal size-tablet lots, high potency would be the result of adding too much active pharmaceutical ingredient during batch formulation (digoxin in this case) or uniformity issues.

Data generated by Actavis

The scope of the physical test data for years 2003 – 2007 is illustrated in the tables below. This does not include the checks done at start-up prior to QA giving the approval to start the

batch production. The in-process tests listed below were performed on a per half-hour basis by Production once QA had given start-up approval. The QA in-process tests were performed on an hourly basis, staggered so as not to be taken at the same time as the Production testing. Tables 1 and 2 reflect the number of physical tests performed per lot and the approximate number of tablets tested for each parameter. These figures represent a significant number of tablets tested for physical attributes.

Table 1: In-Process Tests for 0.125 mg Digitek® tablets from 2003 – 2007		
Production (based on 88 line checks over 252 lots)		
	Tests per lot	Total tablets tested
Weight of 10	176	44,352 (groups of 10 tablets)
Thickness	528	133,056 tablets
Hardness	528	133,056 tablets
Appearance	528	133,056 tablets
QA (based on 44 line checks over 252 lots)		
Weight of 1 tablet	880	221,760 tablets
Thickness	440	110,880 tablets
Hardness	440	110,880 tablets
Appearance	450	113,400 tablets

Table 2: In-Process Tests for 0.25 mg Digitek® tablets from 2003 – 2007		
Production (based on 69 line checks over 218 lots)		
	Tests per lot	Total tablets tested
Weight of 10	138	30,084 (groups of 10 tablets)
Thickness	414	90,252
Hardness	414	90,252
Appearance	414	90,252
QA (based on 36 line checks over 218 lots)		
Weight of 1 tablet	720	156,960
Thickness	360	78,480
Hardness	360	78,480
Appearance	360	78,480

Tables 3 and 4 reflect the lab tests performed per lot and the total number of samples tested.

Table 3: Chemistry Lab Tests for 0.125 mg Digitek® tablets from 2003 – 2007		
Total of 252 lots		
	Tests per lot	Total tests
Friability	1	252
Blend uniformity	1 (10 samples)	2520
Content Uniformity	1 (10 samples)	2520
Assay	1	252
Dissolution	1 (6 samples)	1512
Related substances	3	756
Identity	2	504

Table 4: Chemistry Lab Tests for 0.25 mg Digitek® tablets from 2003 – 2007		
Total of 218 lots		
	Tests per lot	Total tests
Friability	1	218
Blend uniformity	1 (10 samples)	2180
Content Uniformity	1 (10 samples)	2180
Assay	1	218
Dissolution	1 (6 samples)	1308
Related substances	3	654
Identity	2	436

Sample size requirements indicated in the United States Pharmacopeia (USP) monograph for Digoxin tablets, USP were followed by Actavis.

The data generated by Actavis for years 2003 – 2007 are summarized below in Tables 5 - 9. The parameters being addressed are those that would likely reflect thick tablets or high-potency tablets. Thus, for thickness issues, tablet weight and tablet thickness are relevant. Blend uniformity, tablet content uniformity and assay are the relevant parameters for potency issues. While tablet hardness, friability, dissolution, related substances and identification will be briefly mentioned in this report, they are not the main data focus. Nevertheless, satisfactory results for those tests further demonstrate the process's ability to consistently produce product meeting its specifications.

All values for all parameters listed fell within the specification acceptance criteria. Wherever available, the ranges of individual values are reported.

Table 5: In-Process Digitek® Tablet Weight Data			
0.125 mg Specification: 0.097 – 0.113 g (for individuals)			
Year	Range of $\bar{x}$	Range of Individuals	Result
2003	0.105 – 0.106 g	0.001 – 0.002 g [1] (range of std. dev.)	pass
2004	0.105 – 0.106 g	0.100 – 0.111g	pass
2005	0.105 – 0.106 g	0.100 – 0.112g	pass
2006	0.105 – 0.106 g	0.100 – 0.111g	pass
2007	0.105 – 0.106 g	0.098 – 0.112g	pass
0.25 mg Specification: 0.114 – 0.126 g (for individuals)			
2003	0.120 – 0.121 g	0.001 – 0.002 g [1] (range of std. dev.)	pass
2004	0.120 – 0.121 g	0.114 – 0.126g	pass
2005	0.120 – 0.121 g	0.115 – 0.126g	pass
2006	0.120 – 0.121 g	0.115 – 0.125g	pass
2007	0.120 – 0.121 g	0.114 – 0.126g	pass
[1] Note: individual values were not available			

Table 6: In-Process Digitek® Tablet Thickness Data			
0.125 mg Specification: 2.00 – 3.00 mm (for individuals)			
Year	Range of $\bar{x}$	Range of Individuals	Result
2003	2.63 – 2.74 mm	0.03 - 0.05 mm [1] (range of std. dev.)	pass
2004	2.65 – 2.73 mm	0.02 - 0.05 mm [1] (range of std. dev.)	pass
2005	2.69 – 2.77 mm	2.00 – 2.97 mm	pass
2006	2.68 – 2.75 mm	2.00 – 2.85 mm	pass
2007	2.67 – 2.74 mm	2.20 – 2.89 mm	pass
0.25 mg Specification: 2.70 – 3.70 mm (for individuals)			
2003	3.11 – 3.20 mm	0.02 - 0.05 mm [1] (range of std. dev.)	pass
2004	3.14 – 3.19 mm	0.02 - 0.04 mm [1] (range of std. dev.)	pass
2005	3.11 – 3.19 mm	3.02 – 3.40 mm	pass
2006	3.10 – 3.18 mm	3.00 – 3.30 mm	pass
2007	3.11 – 3.18 mm	3.00 – 3.48 mm	pass
[1] Note: individual values were not available			

Table 7: In-Process Digitek® Blend Uniformity Data				
0.125 mg				
Year	Range of $\bar{x}$	Range of std. dev.	Specification	Result
2003	97.0 – 100.7 %	0.9 - 3.0%	85.0 – 115.0 % indiv.	pass
2004	93.9 – 100.0 %	0.8 - 3.0%	85.0 – 115.0 % indiv.	pass
2005	96.5 – 100.8 %	0.6 - 3.8%	90.0 – 110.0 % indiv	pass
2006	96.0 – 99.9 %	0.7 - 3.8% (RSD)	90.0 – 110.0 % indiv. RSD ≤ 5.0%	pass
2007	92.3 – 104.1 %	0.4 - 4.0% (RSD)	90.0 – 110.0 % avg. RSD ≤ 5.0%	pass
0.25 mg				
2003	97.8 – 102.2 %	0.8 - 3.2 %	85.0 – 115.0 % indiv.	pass
2004	97.6 – 99.7 %	1.2 - 2.7 %	85.0 – 115.0 % indiv.	pass
2005	96.4 – 101.3 %	0.7 - 3.6 %	90.0 – 110.0 % indiv.	pass
2006	94.8 – 100.0 %	0.8 - 4.5 % (RSD)	90.0 – 110.0 % indiv. RSD ≤ 5.0%	pass
2007	93.2 – 101.6 %	0.8 - 2.9 % (RSD)	90.0 – 110.0 % avg. RSD ≤ 5.0%	pass

Note: the term "RSD" means "relative standard deviation". Like "standard deviation", it is a measure of the variability of data. The RSD is obtained by dividing the standard deviation by the data's average.

Table 8: Finished Product Digitek® Tablet Content Uniformity Data				
0.125 mg				
Year	Range of $\bar{x}$	Range of Individuals; RSD or AV	Specification	Result
2003	97.2 – 100.3 %	94.0 – 104.3 %; 0.9 – 3.0% (RSD)	85.0 – 115.0% & RSD ≤ 6.0%	pass
2004	98.6 – 102.3 %	94.6 – 104.6 % 1.1 – 2.8% (RSD)	85.0 – 115.0% & RSD ≤ 6.0%	pass
2005	97.8 – 100.9 %	93.3 – 105.4 % 0.7 – 2.9% (RSD)	85.0 – 115.0% & RSD ≤ 6.0%	pass
2006	95.8 – 102.2 %	93.6 – 106.1 % 1.0 – 3.1% (RSD)	85.0 – 115.0% & RSD ≤ 6.0%	pass
2007	96.1 – 104.3 %	87.5 – 108.1 % 2.4 – 11.3% (AV)	AV ≤ 15.0% [1]	Pass
0.25 mg				
2003	98.1 – 105.8 %	94.8 – 106.9 % 0.6 – 2.6% (RSD)	85.0 – 115.0% & RSD ≤ 6.0%	pass
2004	98.8 – 100.7 %	93.0 – 105.3% 0.9 – 3.5% (RSD)	85.0 – 115.0% & RSD ≤ 6.0%	pass

Table 8: Finished Product Digitek® Tablet Content Uniformity Data				
2005	96.3 – 101.3 %	93.5 – 103.7 % 0.5 – 3.4% (RSD)	85.0 – 115.0% & RSD ≤ 6.0%	pass
2006	96.9 – 101.1 %	93.3 – 106.3 % 0.8 – 3.8% (RSD) 1.5 – 8.4% (AV)	85.0 – 115.0% & RSD ≤ 6.0%	pass
2007	96.1 – 102.4 %	2.0 – 7.1 % [2] (AV)	AV ≤ 15.0% [1]	pass
[1] Note: Change in USP specification from 85.0 – 115.0% & RSD ≤ 6.0% to AV ≤ 15.0%. AV means "acceptance value". The probability of a lot passing the test is similar between the old and new specifications [2] Note: Range of individual values not available				

Table 9: Finished Product Digitek® Tablet Assay Data		
Specification: 90.0 – 105.0 % of label claim		
0.125 mg		
Year	Assay range	Result
2003	98.3 – 101.2 %	pass
2004	98.8 – 101.1 %	pass
2005	98.7 – 101.7 %	pass
2006	96.6 – 101.7 %	pass
2007	94.6 – 101.9 %	pass
0.25 mg		
2003	98.6 – 102.9 %	pass
2004	98.1 – 101.6 %	pass
2005	98.3 – 102.2 %	pass
2006	96.2 – 102.4 %	pass
2007	94.1 – 100.7 %	pass

Tests for friability, dissolution, related substances and identification were performed on each of the lots summarized above. All test results met acceptance criteria. It should be noted that all dissolution testing met requirements at stage 1 (additional stage testing for dissolution is only required if the obtained values from the first 6 tablets tested do not conform to the USP stage 1 requirements). All hardness test results were within specification except for one value in 2007 (for that year, one tablet out of roughly 49,000 tested).

A data summary for lot 70924A (0.125 mg Digitek® tablets), the lot in which Actavis found a few double-thick tablets follows below. The quantities tested are indicated above in Table 1. As is true for all lots, the QA samples were selected at different time intervals from the Production personnel samples, to provide better representative sampling across the whole lot. From the test results shown below in Table 10, there was nothing unusual about the quality of this lot. Two tablet presses were utilized and data for the two presses are listed separately in the table below. All acceptance criteria were met.

Table 10: Lot 70924A (0.125 mg Digitek® tablets)			
Parameter	Values obtained	Specification	Result
Press 67			
Weight QA	0.101 – 0.111 g	0.097 – 0.113 g	Pass
Weight of 10 Production	1.040 – 1.068 g	1.019 – 1.082 g	Pass
Thickness QA	2.54 – 2.89 mm	2.00 – 3.00 mm	Pass
Thickness Prod.	2.55 – 2.80 mm	2.00 – 3.00 mm	Pass
Appearance QA	No defects reported (230 samples)	Yellow, round, bisected tablet with "B 145" on bisected side	Pass
Appearance Production	No defects reported (258 samples)	See above	Pass

Table 10: Lot 70924A (0.125 mg Digitek® tablets)			
Press 71			
Weight QA	0.101 – 0.111 g	0.097 – 0.113 g	Pass
Weight of 10 Production	1.036 – 1.069 g	1.019 – 1.082 g	Pass
Thickness QA	2.62 – 2.82 mm	2.00 – 3.00 mm	Pass
Thickness Production	2.61 – 2.77 mm	2.00 – 3.00 mm	Pass
Appearance QA	No defects reported (240 samples)	Yellow, round, bisected tablet with "B 145" on bisected side	Pass
Appearance Production	No defects reported (276 samples)	See above	Pass
Laboratory Tests (not press-specific)			
Blend Uniformity	96.4 – 100.8 %; RSD=1.8%	90.0 – 110.0% avg RSD ≤ 5.0%	Pass
Assay	96.0%	90.0 – 105.0%	Pass
Content Uniformity	AV = 4.4% Individuals: 95.4% - 98.4 %	AV ≤ 15.0%	Pass
Note: AV means "acceptance value". See also note 1 in Table 8.			

The data for the lots immediately preceding (70836A) and following (70925A) lot 70924A are summarized below in Tables 11 and 12. Two presses were used. All tests met acceptance criteria.

Table 11: Lot 70836A (0.25 mg Digitek® tablets - used presses 67 & 71)			
Parameter	Values obtained	Specification	Result
Weight QA	0.114 – 0.125 g	0.114 – 0.126 g	Pass
Weight of 10 Prod.	1.200 – 1.216 g	1.176 – 1.224 g	Pass
Thickness QA	3.07 – 3.20 mm	2.70 – 3.70 mm	Pass
Thickness Prod.	3.05 – 3.16 mm	2.70 – 3.70 mm	Pass
Appearance QA	No defects reported (approx. 360)	White, round, bisected tablet with "B 146" on bisected side	Pass
Appearance Prod.	No defects reported (420 samples)	See above	Pass
Parameter	Values obtained	Specification	Result
Blend Uniformity	94.4 – 101.4 % ; RSD = 2.6%	90.0 – 110.0% avg RSD ≤ 5.0%	Pass
Assay	97.4%	90.0 – 105.0%	Pass
Content Uniformity	AV = 4.5% Individuals: 94.9 – 100.5%	AV ≤ 15.0%	Pass
Note: AV means "acceptance value". See also note 1 in Table 8.			

Table 12: Lot 70925A (0.125 mg Digitek® tablets - used presses 70 & 71)			
Parameter	Values obtained	Specification	Result
Weight QA	0.102 – 0.110 g	0.097 – 0.113 g	Pass
Weight of 10 Prod.	1.047 – 1.069 g	1.019 – 1.082 g	Pass
Thickness QA	2.62 – 2.85 mm	2.00 – 3.00 mm	Pass
Thickness Prod.	2.64 – 2.75 mm	2.00 – 3.00 mm	Pass
Appearance QA	No defects reported (470 samples)	Yellow, round, bisected tablet with "B 145" on bisected side	Pass
Appearance Prod.	No defects reported (528 samples)	See above	Pass
Blend Uniformity	95.0 – 102.2% ; RSD = 2.2%	90.0 – 110.0% avg RSD ≤ 5.0%	Pass
Assay	96.8%	90.0 – 105.0%	Pass
Content Uniformity	AV = 3.7% Individuals: 95.5 – 99.6%	AV ≤ 15.0%	Pass
Note: AV means "acceptance value". See also note 1 in Table 8.			

In addition to the three specific lots in the tables immediately above, batch records for 9 other batches were reviewed (lots 60371A, 60777A, 60994A, 70025A, 70148A, 70207A, 70454A, 70559A, 70770A). All tests met acceptance criteria. It should also be mentioned that, in all of the batch records reviewed, all manufacturing steps were correctly performed according to manufacturing record instructions, including the weighing and addition of active and raw materials, and all yields were within specification limits. All the manufacturing records were appropriately signed by those performing and those reviewing the manufacturing operations.

The stability data from 2003 – 2008 (through lots manufactured in 2007), which are not included in the above tables, cover 155 studies; 79 for the 0.125 mg tablets and 66 for the

0.25 mg tablets. The studies include assay, dissolution and related substances testing. Approximately 750 test intervals were reviewed (i.e., 750 assays, 750 dissolution tests, 750 related substances tests). All test results in all of the studies met specification acceptance criteria. All of the dissolution testing passed at stage 1.

Although FDA had cited Actavis on a tablet press qualification (press ID#70, not used in manufacture of lot 70924A), the issues raised concerned the absence of press manufacturer manuals and adequate predetermined operational ranges to use during the qualification. These were relatively minor issues. Subsequently, Actavis did a requalification. (This occurred prior to the manufacture of 0.125 mg Digitek® tablets lot 70924A).

Data generated by other sources

Besides Actavis' own testing, some external sources also performed testing and batch record auditing.
The FDA, as part of their monitoring program, randomly sampled from some Digitek® tablet lots. The data are summarized below in Table 13. These results were all within specification.

Table 13: FDA Sampling Program

Lot # or FDA sample #	Content Uniformity spec. AV ≤ 15.0%	Assay spec. 90.0 – 105.0%	Dissolution spec. USP Pass
70078A (0.125 mg)	AV = 6.3% ; 93.6% - 100.7% (pass)	96.7% (pass)	Passes at stage 1
70298A (0.125 mg)	AV = 2.7% ; 98.8% - 102.2% (pass)	Not performed	Passes at stage 1
70664A (0.25 mg)	AV = 3.7% ; 95.2 – 99.5% (pass)	Not performed	Passes at stage 1
70737A (0.125 mg)	AV = 4.8% ; 95.4 – 100.1% (pass)	Not performed	Passes at stage 1
70811A (0.25 mg)	AV = 7.0% ; 94.0 – 100.6% (pass)	Not performed	Passes at stage 1
7P964 (0.125 mg)	AV = 4.2% ; 97.1 – 102.1% (pass)	Not performed	Passes at stage 1
8A332 (0.25 mg)	AV = 8.3% ; 93.4 – 105.7% (pass)	Not performed	Passes at stage 1
157503 (0.125 mg)	Passes (no other data available)	Not performed	Passes
157504 (0.125 mg)	Passes (no other data available)	Not performed	Passes

Note: AV means "acceptance value". See also note 1 in Table 8.

Some lots of Digitek® tablets were packaged by UDL in unit-dose blisters, utilizing thickness specifications more restrictive than Actavis'. The visual inspection data obtained (which included examination for thick tablets) covered well over 1300 samples. No visual defects were observed. Additionally, dimensional data for 3 lots (71004A1, 71034A1 and 80111A1) were reviewed and all of the samples met the tighter UDL specifications for thickness. Furthermore, UDL periodically had stability studies conducted, which covered

assay and dissolution testing. Data for 31 lots were reviewed, covering 210 test intervals. Results from all test intervals were satisfactory.

In addition, data for 3 lots (60992A1, 61097A1 and 61100A1) which UDL sent out on behalf of Mylan to a contract laboratory (Celsis) for testing were reviewed. Assay testing and dissolution testing were performed. The assays ranged from 99.6% to 102.4% (all passing) and the dissolution testing passed at stage 1.

Raw material data generated by a contract lab (Gibraltar Laboratories) was reviewed. All of the data were for microbiological testing (except one particle size analysis), and all 57 of the lots met the acceptance criteria.

Although generally satisfied by Actavis' responses to the Form 483 cGMP observations, FDA issued a warning letter, requesting that an independent audit of batch records for lots released by Actavis be performed. Quantic was hired to perform the audit. A sampling protocol with defined acceptance criteria was developed and executed. The goal was to determine, based on extensive examination of the sampled batch records if the identity, strength, quality or purity of the Digitek® tablets in the market place were compromised.

Thirty nine complete batch records were reviewed, including five which contained OOS investigations. Quantic noted no deficiencies that would have affected the identity, strength, quality or purity of the Digitek® tablets released to the market place. The report was sent to FDA, with the final update on 12/24/2007. There has been no indication of dissatisfaction by the FDA with the report after nearly 3 years.

Conclusion:

There is a very large amount of data, over a period of years that shows a process consistently producing product that meets all of its acceptance criteria. This is consistent with what one would expect from a validated process using qualified equipment. All of the data support the integrity of the product. Specifically, with regard to double-thickness tablets, none of the thickness data, weight data or visual inspection data suggest that "double-thick" Digitek® tablets were released to the market. With regard to high-potency tablets, none of the blend uniformity, content uniformity or assay data suggest that high-potency Digitek® tablets were released to the market. The massive amount of internal data generated, the controls used to monitor the product, the externally-generated testing data and the review by an external auditor of a significant number of complete Digitek® batch records all provide assurance that the process (and Actavis) was not releasing either double-thickness tablets or high-potency tablets to the market place.

12/9/2010